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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
10/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/628,004	PINTER ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *24, 25, 27, 31-33, 35-41, 43-46, 48, 56-59, 61-68, 71, 72, 74, 78, 109-112, 114-116, 118-123, 133, 135, and 136-138* is/are withdrawn from consideration.

5)☒ Claim(s) *19 and 20* is/are allowed.

6)☒ Claim(s) *1,10-12,15,16,20,52,53,55,69,70,85,88,90,91,94,97,102,104,107 and 139* is/are rejected.

7)☒ Claim(s) *13,14,22 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,10-16,20,22-25,27,31-33,35-41,43-46,48,52,53,55-59,61-72,74,78,85,88,90,91,94,97,102,104,107,109-112,114-116,118-123,133 and 135-139.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 19,20,24, 25,27,28,31-33,35-41,43-46,52,53,55,61-72,74,78,85,88,90.91,94,97,102,104,107,109-112,114-116,118-123,133 and 135-139.

DETAILED ACTION

This action is in response to the papers filed 6/14/2007.

Claims 1, 10-16, 19, 20, 22, 23, 52, 53, 55, 69, 70, 85, 88, 90, 91, 94, 97, 102, 104, 107, and 139 are under consideration.

Claims 24, 25, 27, 31-33, 35-41, 43-46, 48, 56-59, 61-68, 71, 72, 74, 78, 109-112, 114-116, 118-123, 133, 135, and 136-138 are withdrawn.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 20, 22, and 23 were rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining the specific ~~antibody~~ hybridoma ATCC PTA-3002. Deposit of the ~~antibody~~ hybridoma would satisfy the enablement requirements of 35 U.S.C. 112. Applicant's deposit statement in specification does not indicate the extent of public availability.

Applicant provided the required statement and deposit information.

The rejection is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10-14, 16, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107, and 139 were rejected under 35 U.S.C. 102(b) as being anticipated by Burton *et al.* Applicant's arguments were persuasive and the rejection is withdrawn.

Claims 1, 10-14, 16, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107, and 139 were rejected under 35 U.S.C. 102(b) as being anticipated by Pincus *et al.*

Applicant's arguments were persuasive and the rejection is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 10-16, 22, 23, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107, and 139 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kayman *et al.* (US5643756).

Applicant's arguments were persuasive and the rejection is withdrawn.

Double Patenting

Claims 1, 10-13, 15, 16, 22, 23, 53, 55, 69, 70, 85, 88, 90, 91, 97, 102, 104, 107, and 139 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-20 of U.S. Patent No. 6815201. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to antibodies that bind the V1/V2 loop.

Applicant has amended the claims and the rejection is withdrawn.

New Rejections/Objections

Claim Objections

Claims 13, 14, 22, and 23 are objected to because of the following informalities: they depend from a rejected claim. Appropriate correction is required.

Rejections New

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 15, 16, 20, 22, 23, 52, 53, 55, 69, 70, 85, 88, 90, 91, 94, 97, 102, 104, 107, and 139 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses antibodies to V1 loop that are neutralizing to the SF162 strain and does not indicate other cross reactivity, in particular Figures 8 and 9 show the reactivity of the V1 antibodies to only the SF 162 strain and not to other strains in the comparison.

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111), clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). The prior art teaches this a hypervariable region and antibodies to this region did not bind a related test virus (Pincus *et al.*, paragraph spanning pages 2511-2512).

Accordingly, there is evidence that the full scope of the claimed invention was not in Applicant's possession as of the filing date sought.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see Vas-Cath at page 1115).

With the exception of anti V1 loop of strain SF162 of HIV, the skilled artisan cannot envision the encompassed antibodies and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, ((CAFC, 1993) 25 USPQ 2d 1601) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.,((CAFC, 1991) 18 USPQ2d 1016).

Therefore, only antibodies to the V1 loop of SF162 strain of HIV, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10-12, 15, 52, 53, 55, 69, 70, and 139 are rejected under 35 U.S.C. 102(b) as being anticipated by Pincus *et al.*

Pincus *et al.* teach an antibody that binds to the V1 loop (Figure 10) and has neutralizing activity (Figure 9) which was obtained from a lab worker infected with IIIB/LAV.

Where, as here, the Patent Office lacks the facilities to perform comparisons between the claimed material and prior art materials that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989).

Thus, the claims are anticipated by Pincus *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 16, 85, 88, 90, 91, 94, 97, 102, 104, and 107 rejected under 35 U.S.C. 103(a) as being unpatentable over Pincus *et al.*

The claims are drawn to an anti V1 loop antibody including monoclonal, fragments, labeled, and various manipulations of antibodies.

Pincus *et al.* teach an antibody that binds to the V1 loop (Figure 10) and has neutralizing activity (Figure 9) which was obtained from a lab worker infected with IIIB/LAV.

Pincus *et al.* do not teach monoclonal antibodies of the V1 antibody or the antibody types (antigen binding fragments, bispecific, labeled etc).

One of ordinary skill in the art at the time of invention would have been motivated to make monoclonal antibodies to the V1 loop because it was unexpected to find neutralizing antibodies directed to it (paragraph spanning pages 2511-2512).

One of ordinary skill in the art at the time of invention would have been able to use the known V1 sequences to make monoclonal antibodies and having the monoclonal antibodies to the V1 loop, it would have been obvious to make other forms of antibody as well as label antibodies for use in assays.

Thus, it would have been *prima facie* obvious at the time of invention to make monoclonal antibodies and forms thereof of the V1 loop binding specificity taught by Pincus *et al.* with the expectation of success knowing that it is routine to make monoclonal antibodies as well as various forms of antibodies and to label antibodies for use in assays.

Conclusion

Allowable Subject Matter

Claims 13, 14, 22, and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 19 and 20 are drawn to an allowable deposit.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Myron G. Hill
Patent Examiner
12 October 2007

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